WHAT IS CLAIMED IS:

1. A composition comprising stable particles of a surface modified water-insoluble biologically active substance of a mean size in the range of 0.01 to 10 micrometers, which particles are dispersed in a non-aqueous carrier system comprised of:

   (a) a non-aqueous medium in which the biologically active substance is not soluble or is poorly soluble; and

   (b) a surfactant system consisting of at least one surfactant which is soluble in the non-aqueous medium and which absorbs to the surface of the biologically active substance; and

   (c) optionally a quantity of not more than about 10% of the total weight of said composition of one or more hydrophilic substance that provides a self-dispersing property to said composition.

   wherein said composition can self-disperse upon addition to an aqueous medium to form a suspension comprising components of the non aqueous carrier system and stable particles of said water-insoluble biologically active substance wherein said particles have a size in the range of 0.01 to 10 micrometer and have associated therewith on the surface at least a portion of said surfactant system.

2. A composition comprising a water-insoluble biologically active substance mixed with a non-aqueous carrier system, wherein said carrier system comprises:

   (a) a non-aqueous medium in which said water-insoluble biologically active substance is soluble; and

   (b) a surfactant system consisting of at least one surfactant; and

   (c) optionally a quantity of not more than about 10% of the total weight of said composition of one or more hydrophilic substance that provides a self-dispersing property to said composition;

   wherein said composition can self-disperse upon addition to an aqueous medium to form a suspension comprising components of the non aqueous carrier system and stable particles of said water-insoluble biologically active substance wherein said particles

have a mean size in the range of 0.01 to 10 micrometer and have associated therewith on the surface at least a portion of said surfactant system.

3. The compositions of claim 1 and 2 where the non-aqueous carrier system consists of:

(a) at least one non-aqueous medium component selected from the group consisting of oils derived from vegetable or animal origins; vegetable oils; fish oils; fish oil free fatty acids; oleic acid; linoleic acid; poly-unsaturated fatty acids; fatty acid esters; triglycerides; caprilic/capric triglyceride; caprylic/capric/linoleic triglyceride; synthetic medium chain triglycerides having C_{8-12} fatty acid chains; synthetic triglycerides; Miglyol 810, Miglyol 812, Miglyol 818, Miglyol 829, Miglyol 840; diglycerides; monoglycerides; monoglyceride and diglyceride free fatty acids; fatty acid esters; propylene glycol dicaprylate/caprate; linoleic acid ethyl ester; EPAX6000FA; EPAX4510TG; cholesteryl fatty acid esters; C_{12-18} fatty acid monoglycerides, C_{12-18} fatty acid diglycerides, and C_{12-18} fatty acid triglycerides prepared from soybean oil, almond oil, sunflower oil, olive oil, and corn oil with glycerol; pharmaceutically acceptable monohydric alcohols; pharmaceutically acceptable alkanols; pharmaceutically acceptable dihydric alcohols; glycols; pharmaceutically acceptable polyhydroxy compounds; glycerin; pharmaceutically acceptable aromatic esters; benzyl benzoate; diethyl phthalate; propyl gallate; triacetin; diacetin; monoacetin; triethyl citrate; water soluble organic solvents; propylene carbonate; glycofurol; dimethyl isosorbide; dimethyl isoidide; dimethyl isomannide; pharmaceutically suitable hydrophobic organic solvents; hydrofluorocarbons; and perflubron; and

(b) at least one surfactant component selected from the group consisting of natural or synthetic amphiphilic agents; phospholipids; cholesterol; nonionic surfactants; polyoxyethylene fatty alcohol ethers; sorbitan fatty acid esters; polyoxyethylene sorbitan fatty acid esters; Tweens; sorbitan esters; Myrj glycerol esters; glycerol triacetate; triacetin; polyethylene glycols; cetyl alcohol; cetostearyl alcohol; stearyl alcohol; poloxamers; polaxamines; polyoxethylene castor oil derivatives; Cremophors; vitamin E; D-alpha-tocopheryl polyethylene glycol 1000 succinate; vitamin E TPGS; PEG glyceryl fatty acid esters; PEG-8 glyceryl caprylate/caprate; Labrasol; PEG-4 glyceryl caprylate/caprate; Labrafac Hydro WL 1219; PEG-32 glyceryl laurate; Gelucire 44/14; PEG-6

glyceryl mono oleate; Labrafil M 1944 CS; PEG-6 glyceryl linoleate; Labrafil M 2125 CS; propylene glycol mono fatty acid esters; propylene glycol di-fatty acid esters; propylene glycol laurate; propylene glycol caprylate/caprate; diethylene glycol monoethyl ether; transcutol; sorbitan fatty acid esters; Span fatty acid esters; Span 20; monoglycerides; acetylated monoglycerides; glycerol monooleate; glycerol monostearate; mono-acetylated monoglycerides; di-acetylated monoglycerides; monoacetin; diacetin; carbomers; Carbopol; anionic surfactants; fatty acid salts; bile salts; potassium laurate; triethanolamine stearate; sodium lauryl sulfate; alkyl polyoxyethylene sulfates; sodium alginate; dioctyl sodium sulfosuccinate; sodium carboxymethylcellulose; calcium carboxymethylcellulose; cationic surfactants; pharmaceutically acceptable quaternary ammonium compounds; benzalkonium chloride; cetyltrimethylammonium bromide; and lauryldimethylbenzylammonium chloride; substituted cellulose derivatives; methylcellulose; hydroxycellulose; hydroxy propylcellulose; hydroxy propylmethylcellulose; noncrystalline cellulose; sodium carboxymethyl cellulose; polyethylene glycol; PEG; PEG 300; PEG 400; PEG 600; PEG 1000; PEG 1500; PEG 3400; Carbowax; Lutrol E; Hodag PEG; and

(c) optionally at least one hydrophilic component selected from the group consisting of low-molecular weight monohydric alcohols; low-molecular weight polyhydric alcohols; ethanol; glycols; glycerol; and mixtures thereof.

4. Compositions of claim 1 and 2 in which the surfactant system comprises at least one phospholipid selected from the group consisting of saturated phospholipids, unsaturated phospholipids, synthetic phospholipids, natural phospholipids, and combinations thereof.

5. Compositions of claim 1 and 2 in which the non-aqueous medium comprises an oil selected from the group consisting of a vegetable oil, an animal oil, a synthetic oil, a free fatty acid oil, a poly-unsaturated fatty acid oil, a fatty acid ester oil, a triglyceride oil, a diglyceride oil, a monoglyceride oil, and combinations thereof.

6. The composition of claim 1 where the stable particles are produced in a size reduction unit operation selected from the group consisting of homogenization, milling, microfluidization, precipitation, recrystallization, anti-solvent precipitation, and precipitation from an expanding supercritical fluid.

7. The homogenization unit operation of claim 6 which employs a high pressure homogenizer or microfluidizer selected from the group consisting of an Avestin homogenizer or microfluidizer, a Niro homogenizer or microfluidizer, a Rannie homogenizer or microfluidizer, a Gaulin homogenizer or microfluidizer, a homogenizer or microfluidizer comprising of a homogenizing valve made of ceramic materials, and a homogenizer or microfluidizer comprising of a homogenizing valve made of diamond materials.

8. Compositions of claims 1 and 2 wherein the concentration of the biologically active substance is sufficient for use in sustained or controlled delivery of the active substance.

9. Compositions of claims 1 and 2 further comprising one or more pharmaceutical excipient useful for peroral, parenteral, transdermal, inhalation, or ophthalmic administration of the biologically active substance.

10. Compositions and processes according to claims 1 and 2 wherein the biologically active substance is selected from the group consisting of an antihypertensive drug; nifedipine; an anticholinergic drug; ursodiol; a drug for treating a gastro-intestinal disorder; budesonide; a hormone; an antineoplastic drug; peclitaxel; camptothecin; a derivative of peclitaxel; a derivative of camptothecin; an NSAID; piroxicam; an anti-fungal agent; itraconazole; an anti-viral agent; acyclovir; a derivative of acyclovir; a cholesterol controlling agent; fenofibrate; an immuno-suppressive peptide; cyclosporine; a protein used in the treatment of diabetes; insulin; and a derivative of insulin.

11. The compositions of claims 1 and 2 contained in a capsule selected from the group consisting of a hard gelatin capsule, a soft gelatin capsule, and a starch capsule, which capsule optionally comprises a pharmaceutically acceptable coating for controlling the release of the biologically active substance.

12. The compositions of claims 1 and 2 contained in a tablet, which tablet optionally comprises a pharmaceutically acceptable coating for controlling the release of the biologically active substance.

13. The compositions of claims 1 and 2 where the aqueous medium is selected from the group consisting of water; buffered water; phosphate buffered water; phosphate buffered saline; citrate buffered water; acetate buffered water; water buffered with pharmaceutically acceptable pH controlling agents; water containing salts; water containing sodium chloride; water containing pharmaceutically acceptable salts; water containing soluble agents for lyoprotection; water containing soluble agents for cryoprotection; water containing dextrose; water containing mannitol; water containing trehalose; water containing sucrose; water containing sorbitol; water containing pharmaceutically acceptable lyoprotectants; water containing pharmaceutically acceptable cryoprotectants; water containing polyhydroxy-containing compounds; water containing sugars; water containing polyols, and mixtures thereof.

14. The compositions of claims 1 and 2 where the aqueous medium is selected from the group consisting of a biological fluid; blood; plasma; saliva; urine; a protein-containing solution; an aqueous suspension of a protein; lymph fluid; semen; vaginal fluid; lachrymal fluid; nasal fluid; synovial fluid; cerebral fluid; cerebralspinal fluid; amniotic fluid; pancreatic fluid; pulminary fluid; ascites fluid; fluid from a cyst; gastric fluid; intestinal fluid; a fluid removed from a patient; a diluted biological fluid; a concentrated biological fluid; and a mixture of biological fluids from one or more patients.

15. The compositions of claims 1 and 2 where the aqueous medium contains one or more surface active agent.

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